UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,571	12/31/2001	Etsuro Ogata	04853.0086	7887

22852 7590 04/26/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,571	OGATA ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12-14,18,23,24 and 26-30* is/are pending in the application.

4a) Of the above claim(s) *4-8,12,13,18,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9,10,14 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/04/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on 02/28/2006 has been entered. Claims 3, 9, and 27 have been amended. Claims 1, 3, 9, 10, 14, and 26-30 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejection of claims 1, 3, 9, 10, and 14 under 35 U.S.C. 102(b) as being anticipated by Grunfeld et al. (WO 96/39184, December 12, 1996) has been withdrawn in view of Applicants' argument.

The objection of claim 9 has been withdrawn in view of amended claim.

Information Disclosure Statement

The information disclosure statement filed on 04/04/2006 has been considered by the Examiner and a signed copy of the substitute form PTO-1449 is attached to the office action.

Claim Rejections Under 35 USC § 102

The rejection of claims 26-30 under 35 U.S.C. 102(b) as being anticipated by Grunfeld et al. (WO 96/39184, December 12, 1996) is maintained.

Beginning at page 8 of Applicants' response filed on 02/28/2006, Applicants argue that Grunfeld et al. do not disclose or teach a human antibody and do not claim a human antibody.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Grunfeld et al. clearly disclose a human antibody. For example, at page 5, lines 29-37, Grunfeld et al. states " the polyclonal or monoclonal antibodies may be raised in rabbits, mice, or other animals or tissue cultured cells or can be products of cells of human origin. They may also be produced of recombinant DNA technology either in a form identical to that of the native antibody or as chimeric molecules, constructed by recombination of **antibody molecules of man** and animal origins or in other forms chosen to make the antibodies most suitable for use in therapy".

Moreover, Grunfeld et al. teach the therapeutic use of a human antibody (from the bottom of page 1 to top of page 2). For example, beginning at page 1, line 35, Grunfeld et al. state: "Murine and human monoclonal antibodies directed against the core lipopolysaccharide of the endotoxin have been reported to exert protection during Gram-negative bacterial sepsis in animals". Beginning at page 2, line 12, Grunfeld et al.

state: "In addition, human monoclonal antibodies to *p. aeruzinosa exotoxin A* and exoenzyme S have been described as useful for this purpose".

Furthermore, there is no requirement for a prior art to claim the subject matter under the patent law.

Accordingly, the teachings of Grunfeld et al. anticipate claims 26-30.

Claim Rejections under 35 U.S.C. §103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(ii). Claims 1, 3, 9, 10, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunfeld et al. (WO 96/39184, December 12, 1996) in view of Sato et al. (US2002/0165363 A1, Publication Date: November 7, 2002; earliest priority date: May 15, 1997).

Grunfeld et al. teach treatment of systematic inflammatory response syndrome, including septicemia (1st paragraph of page 1; line 2 of page 3), with an anti-PTHrP antibody (Abstract; lines 5-26 of page 1). The septicemia, which is listed in canceled

claim 11 as one of the diseases mediated by PTHrP-cytokine (IL-6), necessarily reduces quality of life (QOL) of patients.

Grunfeld et al. fail to explicitly teach treating septicemia with a humanized antibody.

Sato et al. teach a therapeutic agent for cachexia, an anti-PTHrP antibody, including a humanized #23-57-137-1 antibody (see, e.g., claims 5-6; [0013]; and Example 4), which inhibits the binding of PTHrP to its receptor (see, e.g., [0010]). Treatment of cachexia with the humanized #23-57-137-1 anti-PTHrP antibody increased survival rate (Fig. 1) and reduced the loss of body weight in mice with cachexia (Fig. 3). The humanized #23-57-137-1 antibody, which is the same antibody disclosed in the instant application (see page 38 of the instant specification), inhibits the binding of PTHrP to PTHrP type 1 receptor.

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to treat septicemia by administering to a human patient a humanized #23-57-137-1 antibody with a reasonable expectation of success. One would have been motivated to do so because the antigenicity of the humanized antibody against a human body is reduced as taught by Sato et al. ([0045] and [0051]).

Claim Objections

The objection to claims 9, 10, 28, and 29 are maintained because they recite non-elected subject matter (species). Since independent claims 1 and 26 are drawn to a method of treatment of septicemia with a PTHrP antibody, PTH-cytokine cascade does not appear to be related to septicemia. Thus, only PTHrP-cytokine cascade should be recited in claims 9 and 28. In addition, it is suggested that only the cytokines that are involved in septicemia be listed in claims 9, 10, 28, and 29. Appropriate correction is required.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li, Ph.D.
Primary Examiner
April 22, 2006

RUIXIANG LI, PH.D.
PRIMARY EXAMINER